UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Norfolk Division

AMERICAN SALES COMPANY, LLC,
on behalf of itself and all others similarly situated,

Plaintiffs,

v. **Civil Action No. 2:14cv361**

PFIZER, INC., *et al.*,

Defendants.

MAGISTRATE JUDGE'S REPORT AND RECOMMENDATION

This Report recommends certifying a class action comprised of direct purchasers of the pharmaceutical drug Celebrex to resolve antitrust claims against the drugmaker, Pfizer, Inc. ("Pfizer"). The Motion to Certify Class (ECF No. 191)[1] filed by Plaintiffs American Sales Company, LLC ("ACS"), Rochester Drug Co-Operative, Inc. ("RDC"), and Cesar Castillo, Inc. (collectively "Plaintiffs") on behalf of similarly situated buyers asserts that Defendants, Pfizer and its affiliates (collectively "Pfizer" or "Defendants"), violated federal antitrust law by fraudulently securing a reissue patent for Celebrex, enabling Pfizer to profit under an extended period of patent protection. As a result of the delayed entry of generic drugs into the market, the Plaintiffs allege overcharges for both brand-name and generic Celebrex. Because a sufficiently numerous class meets the requirements of Federal Rule of Civil Procedure 23, this Report recommends that a partial class of thirty-two (32) members be certified and allowed to proceed with this class action suit.

[1] The Motion was referred to the undersigned Magistrate Judge pursuant to 28 U.S.C. § 636(b)(1)(B) and Federal Rule of Civil Procedure 72(b). (ECF No. 225).

I. BACKGROUND

Pfizer is a multi-national pharmaceutical company that researches, develops, manufactures, and distributes brand-name medications used around the world. One of Pfizer's affiliates, Greenstone, also manufactures generic versions of its drugs. The subject of this litigation is a Pfizer drug commonly known as Celebrex. The active ingredient in Celebrex is celecoxib, and the medicine is generally used to relieve pain and inflammation. Plaintiffs and the proposed class members are a group of direct purchasers, primarily drug wholesalers, who buy brand-name and generic drugs to be sold nationwide in pharmacies and online. Each of the proposed class members bought either brand-name or generic Celebrex, or both, between May 30, 2014, and March 2, 2015, the period of the claimed overcharges.

A. Patent Prosecution and Prior Litigation

Although recited in detail elsewhere,[2] a brief summary of the reissue patent prosecution and subsequent litigation is necessary to understand the allegations underlying this suit. In the 1990s, Pfizer acquired several patents protecting celecoxib, including U.S. Patent Nos. 5,466,823 (the "'823 patent"), 5,563,165 (the "'165 patent"), and 5,760,068 (the "'068 patent"). All three patents disclosed the utility of celecoxib. Both the '165 patent and the '823 patent expired in May 2014. But as a result of its different prosecution history, the '068 patent was not set to expire until June 2, 2015. Before the '068 patent reached its expiry, it was invalidated in 2008 on the basis of obviousness-type double patenting over the '165 patent.[3] Pfizer, Inc., et al. v. Teva Pharm. USA, Inc., 518 F.3d 1353 (Fed. Cir. 2008). The court also found that the § 121

[2] See, e.g., Op. and Order on Pls.' Mot. to Compel (ECF No. 175); Order on Defs.' Mot. to Dismiss (ECF No. 73); G.D. Searle LLC v. Lupin Pharmaceuticals, Inc., No. 2:13cv121, 2014 WL 9869122 (E.D. Va. Mar. 12, 2014).

[3] "Obviousness-type double patenting" refers to the prohibition on extension of one patent's term through the issuance of a second patent that is insufficiently distinct from the first. See Boehringer Ingelheim Int'l GHBH v. Barr Laboratories, Inc., 592 F.3d 1340, 1346 (Fed. Cir. 2010).

"safe harbor provision" did not apply to the '068 patent because Pfizer prosecuted the '068 patent as a continuation-in-part (CIP) application rather than as a divisional.[4]

Pfizer then sought reissue of the '068 patent, partly to preserve the extra period of exclusivity over Celebrex. The reissue proceedings were protracted but eventually led to U.S. Patent No. RE 44,048 (the "RE '048 patent"). Pfizer's prosecution of the application leading to the RE '048 patent led to this suit. Plaintiffs allege that Pfizer fraudulently secured the RE '048 patent by misrepresenting facts related to the original prosecution history of the '068 patent, and its purpose for seeking reissue. Specifically, Pfizer filed for reissue to correct the claimed "error" of originally prosecuting the '068 patent as a CIP application. According to Plaintiffs, this amounted to fraud on the Patent Trademark Office ("PTO") because Pfizer had deliberately chosen to prosecute a CIP application, and thus its failure to file as a divisional was not an "error." Plaintiffs also allege Pfizer made other misrepresentations intended to conceal its intent. These false claims, the Complaint alleges, allowed Pfizer to improperly extend the period of patent protection over Celebrex. As a result, Plaintiffs argue they were forced to purchase Celebrex at inflated prices because the date when cheaper generic versions of the drug would have been available was improperly delayed.

Because Pfizer's '068 patent had been ruled invalid in 2008, and its other patents were set to expire in May 2014, several manufacturers had begun preparing to enter the market with a generic version of Celebrex. On the same day the RE '048 patent issued, Pfizer filed a lawsuit against five generic-drug manufacturers, alleging infringement of the newly reissued patent. The defendant-manufacturers filed counterclaims for invalidity, arguing that the RE '048 patent was

[4] The "safe harbor provision," 35 U.S.C. § 121, protects patents from invalidation on double patenting grounds under certain circumstances. For the safe harbor to apply, two requirements must be met: (1) the patent must issue from a divisional application rather than a CIP application, and (2) the divisional application must be a result of a PTO restriction requirement. Geneva Pharm., Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1382 (Fed. Cir. 2003).

improperly issued because the error Pfizer sought to remedy – issuance from a CIP – could not be corrected on reissue. The manufacturers also argued the RE '048 patent – like its predecessor, the '068 patent – was invalid for obviousness-type double patenting and not subject to safe-harbor protection. The companies moved for summary judgment, which the district court promptly granted. See G.D. Searle LLC v. Lupin Pharm., Inc., No. 2:13cv121, 2014 WL 9869122 *1 (E.D. Va. Mar. 12, 2014). Pfizer appealed the ruling, and the United States Court of Appeals for the Federal Circuit affirmed the district court's invalidation of the patent on obviousness-type double patenting grounds, but did not reach the question of whether the error Pfizer alleged was correctable on reissue. See G.D. Searle LLC v. Lupin Pharm., Inc., 790 F.3d 1349 (Fed. Cir. 2015). In between the district court's rejection of the RE '048 patent and the Federal Circuit's decision, Pfizer negotiated settlements with three of the generic manufacturers. The terms of the settlement agreements permitted generic competition from four manufacturers beginning in December 2014, just over six months after the other Celebrex patents had expired. When generic competition did begin in December 2014, a total of five manufacturers – Teva, Lupin, Mylan, Watson, and Pfizer affiliate Greenstone – launched generic products.

B. The Proposed Class Action

Plaintiffs filed the instant class action suit against Pfizer alleging that it monopolized the market for Celebrex by fraudulently securing the RE '048 patent. See Second Amend. Compl. ¶ 221 (ECF No. 185). Specifically, Plaintiffs assert that Pfizer's procurement and enforcement of the RE '048 patent wrongfully delayed entry of generic celecoxib drugs into the marketplace, causing them to purchase brand-name Celebrex from Pfizer at a higher cost during the "delay period." The "delay period" is defined as the period between May 30, 2014 – when generics would have entered the market but for Pfizer's alleged anticompetitive conduct – and December

2014, when generics actually entered the market. Plaintiffs also seek to recover for overcharges incurred in the three months following generic entry as prices fell to their fully competitive level. They argue that certain generic-only buyers of celecoxib suffered overcharges because they would have obtained a greater decrease in the price for the generics over time but for the delayed entry. In sum, they seek damages for this entire "overcharge period" between May 30, 2014 and March 2, 2015, three months after generic entry. As a result, Plaintiffs now move to certify the following class:

> All persons or entities in the United States and its territories and possessions who purchased brand or generic versions of Celebrex directly from any manufacturer at any time during the period May 30, 2014 through March 2, 2015 (the "Class Period"). Excluded from the Direct Purchaser Class are Defendants and their officers, directors, management, employees, subsidiaries, or affiliates, and all federal governmental entities. Also excluded are persons or entities who purchased only generic versions of Celebrex and did not obtain decreasing prices on those generic versions.

Pls.' Mem. Supp. Mot. to Certify Class 2 (ECF No. 192). Plaintiffs have identified forty-four (44) prospective members of this class, all purchasers of either brand or generic Celebrex during the class period. See Expert Report of Jeffrey J. Leitzinger, Ph.D. [hereinafter "Leitzinger Report"] ¶ 31 n.3 (ECF No. 232).[5]

1. Regulatory Framework and Market for Generic Drugs

The pharmaceutical industry depends upon the creation and monetization of intellectual property. See id. at ¶ 10. When manufacturers create new drugs, their intellectual property is protected in multiple ways, including patents and regulation which restrict competition. Id. The periods of exclusivity conferred by these federal regulations permit drugmakers to profitably invest in new medicines. Despite well-defined limits on these periods of exclusivity, regulatory obstacles were still preventing cheaper generics from reaching the market when, in the 1980s,

[5] Defendants have filed a Motion to Exclude the Declaration and Testimony of Dr. Jeffrey Leitzinger (ECF No. 257). The court will address that Motion in a separate Order.

Congress passed the Hatch-Waxman Act. The purpose of the Act was to expedite the entry of cost-saving generics to the market immediately upon the expiration of a patent's protection. Under the Act, generic manufacturers can begin developing and testing generic versions of patented drugs before their patents expire without facing liability for patent infringement. Id. at ¶ 11. The Act also authorized an abbreviated process for obtaining FDA approval of generic drugs, and encouraged generic manufacturers to begin preparing to market their products by providing protection from infringement for certain clinical tests which occur prior to expiration. See 21 U.S.C. § 355(j). Five years after the Food and Drug Administration ("FDA") approves a new drug, generic manufactures can file an Abbreviated New Drug Application ("ANDA") to obtain approval for bringing their generics to market after the patents protecting the brand-name drug expire. Leitzinger Report ¶ 11 (ECF No. 232). When a generic product meets FDA safety and efficacy standards it is given an "AB" rating, which indicates to physicians, pharmacists, and consumers that the product is essentially identical in terms of therapeutic effect and safety to the brand-name version. Id. at ¶ 13.

The ANDA process allows generic manufacturers to avoid much of the cost and time associated with developing new drugs and obtaining regulatory approval to market them. Id. at ¶ 14. As a result, generic drugs typically enter the market at a much lower price than the original product. Id. The phenomenon of falling prices following entry of an AB-rated generic is rapid, dramatic, and well documented. Id. at ¶ 15. In this case, data from the generic manufacturers of celecoxib and from Pfizer's own sales figures establish a dramatic drop in the price paid for celecoxib, with generics accounting for 80% of all prescriptions within two quarters of generic entry. Id. at ¶¶ 28-30. Plaintiffs' expert also contends that Pfizer substantially discounted brand-name Celebrex in an effort to retain some of its market share. Id. ¶ 30. The Hatch-Waxman Act

has therefore become a "powerful engine" for reducing prescription drug prices for consumers. Id. This boon for consumers and generic manufacturers makes "conduct that delays or limits generic competition" harmful to purchasers of generic drugs. Id. at ¶ 16. By keeping generic versions of Celebrex out of the market, Pfizer could avoid the drastic reduction in market share and profitability Celebrex would face upon losing exclusivity.

Plaintiffs allege that Pfizer fraudulently obtained the RE '048 patent and then sued generic manufactures to prevent their timely market entry, thus creating a delay period of just over six months where purchasers were required to continue buying brand-name Celebrex. See Pls.' Second Amend. Compl. ¶¶ 202-241 (ECF No. 185); Pls.' Mem. Supp. Mot. to Certify Class 2-3 (ECF No. 192). According to Plaintiffs' expert, Dr. Leitzinger, this delay created an "overcharge period," which includes the six-month actual delay to generic entry and the three subsequent months it took for "generic entry [to] finally produce the full savings associated with generic competition." Leitzinger Report ¶ 37 n.56 (ECF No. 232).

2. Proposed Class Members

Plaintiffs have proposed a class of forty-four (44) members made up of entities that purchased brand-name Celebrex and/or generic versions of the drug during the approximately nine-month "overcharge period." Pls.' Mem. Supp. Mot. to Certify Class 2 (ECF No. 192). The actual purchasing history (i.e., brand vs. generic purchases) of the proposed members differs, and the members can be separated into three distinct categories: Brand and generic purchasers, brand-only purchasers, and generic-only purchasers. See Expert Report of Dr. Pierre-Yves Cremieux [hereinafter "Cremieux Report"] Ex. 4 (ECF No. 241-1).

Entities that purchased brand and generic Celebrex during the overcharge period make up the largest category of direct purchasers with twenty-five (25) proposed members.[6] Id. Each of the twenty-five members purchased brand-name Celebrex during the six-month delay period. Id. The twenty-five brand/generic purchasing members also made generic purchases in the three months following generic entry. Id. The next category consists of eight (8) brand-only purchasers[7] that did not buy any generic celecoxib during the ten-month overcharge period. Id. Of the eight brand-only purchasers, three bought Celebrex before and after generic entry; three only bought Celebrex before generic entry;[8] and two only bought the brand-name drug after generic entry. Id. The final category consists of ten (10) generic-only purchasers[9] who made no brand-name purchases during the overcharge period.[10] Id.

These forty-four proposed class members were allegedly harmed by overcharges resulting from the delay in generic entry. Specifically, Plaintiffs' expert states that the proposed class members would have paid less for celecoxib drugs in three ways: (1) "much of the brand Celebrex purchase volume during the delay period would have been replaced with generics at

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[6] The twenty-five entities in brand/generic purchaser category include: Amerisource Bergen, ANDA/Watson, Bellco, Burlington Drug, Capital Wholesale, Cardinal Health, Dakota Drug, Drogueria Betances, Drugs Unlimited, Express Scripts, Frank W Kerr, H. D. Smith Wholesale, Harvard Drug, Louisiana Wholesale, Mckesson, Miami Luken, Morris & Dickson, North Carolina Mutual Wholesale Drug, PBA Health, Prescription Supply, R&S Northeast, Rochester Drug Co-Operative, Smith Drug, Valley Wholesale Drug, and Value Drug. Cremieux Report Ex. 4 (ECF No. 241-1).

[7] The eight brand-only purchasers are: Cesar Castillo, DMS Pharmaceutical, Drogueria Bayamon, Drogueria Las Rosas, Henry Schein, Lifeline Pharmaceuticals, PSS World Medical, and Super Farmacia Nelia. Cremieux Report Ex. 4 (ECF No. 241-1).

[8] Plaintiffs' counsel proffered during the hearing on this Motion that at least one brand-only purchaser, PSS World, had made a generic purchase. Tr. of Hr'g on Mot. to Certify Class 27:1-14 (ECF No. 356).

[9] The ten generic-only purchasers are: Associated Pharmacies, Auburn Pharmaceuticals, Bloodworth Wholesale, Genetco, Independent Pharmacy Cooperative, Keysource Medical, Quest Pharmaceuticals, Richie Pharmacal, Top RX, and Walmart. Cremieux Report Ex. 4 (ECF No. 241-1).

[10] There are eleven (11) entities identified in Dr. Cremieux's exhibits as being generic-only purchasers. And indeed, one of the eleven entities, AHOLD USA, only shows manufacturer purchasing data for generic products after the delay period. However, AHOLD USA, the parent company of representative Plaintiff American Sales Company, is a partial assignee of Mckesson Corp. for brand-name Celebrex purchases. Tr. of Hr'g on Mot. to Certify Class 67:14-25, 68:1-18 (ECF No. 356). Accordingly, the court has excluded AHOLD USA from any purchaser category.

much lower prices;" (2) "the remaining Celebrex purchases would have occurred at lower average prices;" and (3) "generics purchased following actual generic entry would have had still-lower prices by virtue of the fact that, in the but-for world generic competition would have started earlier." Leitzinger Report ¶ 37 (ECF No. 232).

3. Aggregated Damages Model

According to Plaintiffs, the antitrust impact or overcharge paid by all of these class members can be shown through class-wide proof. Leitzinger Report ¶¶ 35-38 (ECF No. 232). Specifically, Dr. Leitzinger's formula for calculating class-wide aggregate overcharges relies upon data obtained from Pfizer, the generic manufacturers, as well as industry literature evaluating similar generic/brand substitution at the end of patent exclusivity. Id. at ¶¶ 20-29. The model begins by calculating "but-for" prices per milligram of celecoxib utilizing the purchase volumes and prices paid after generic entry and back-casting them to the earlier entry date. Id. at ¶¶ 39-42. Dr. Leitzinger also calculated an average price actually paid from the same data and compared this but-for average to the actual price paid per milligram of celecoxib to arrive at an average overcharge per each unit sold during the delay period. Leitzinger Report Ex. 5 (ECF No. 232). He also calculated a second average overcharge for the period after generics entered the market. After applying the purchase volumes for each period, Dr. Leitzinger estimated the total average overcharge to be $845 million dollars – $791 million during the delay period and $54 million after generics entered the market in December, 2014.

II. LEGAL STANDARD

To obtain class certification, Plaintiffs must meet all four requirements of Federal Rule of Civil Procedure 23(a), and at least one of the requirements of Rule 23(b). See Gunnells v. Healthplan Servs., Inc., 348 F.3d 417, 423 (4th Cir. 2003). In this case, Plaintiffs seek

certification of the proposed class under Rule 23(b)(3), which requires that common questions of law predominate. See Fed. R. Civ. P. 23(b)(3). The party seeking certification bears the burden of proof, and each requirement of Rule 23 must be satisfied by a preponderance of the evidence. In re Hydrogen Peroxide Antitrust Litig., 552 F.3d 305, 320 (3d Cir. 2008).

Class actions are an exception to the general rule that "litigation is conducted by and on behalf of the individual named parties only." Wal-Mart Stores, Inc. v. Dukes, 564 U.S. 338, 348 (2011). In Wal-Mart, the Supreme Court stated that "Rule 23 does not set forth a mere pleading standard. A party seeking class certification must affirmatively demonstrate his compliance with the Rule – that is, he must be prepared to prove that there are in fact sufficiently numerous parties, common issues of law or fact, etc." Id. at 350 (emphasis in original). In deciding a motion for class certification, a court must closely examine the relevant facts, even if those facts "tend to overlap with the merits of the case." Thorn v. Jefferson-Pilot Life Ins. Co., 445 F.3d 311, 319 (4th Cir. 2006). "Certification is proper only if 'the trial court is satisfied, after a rigorous analysis, that the prerequisites of Rule 23(a) have been satisfied.'" Wal-Mart, 564 U.S. at 350-51 (quoting Gen. Tel. Co. of the Sw. v. Falcon, 457 U.S. 147, 160 (1982)).

The "rigorous analysis" also extends to disputes between experts. See In re Titanium Dioxide Antitrust Litig., 284 F.R.D. 328, 336 (D. Md. 2012). "Resolving expert disputes in order to determine whether a class certification requirement has been met is always a task for the court – no matter whether a dispute might appear to implicate the 'credibility' of one or more experts. . . ." In re Hydrogen Peroxide, 552 F.3d at 323-24. However, "[a] court's determination that an expert's opinion is persuasive or unpersuasive on a Rule 23 requirement does not preclude a different view at the merits stage of the case." Id. at 324.

III. DISCUSSION

A. Rule 23(a)

1. Numerosity

The first prong of Rule 23(a) requires that the proposed class be "so numerous that joinder of all members is impracticable." Fed. R. Civ. P. 23(a)(1). The Fourth Circuit has held that "[n]o specified number is needed to maintain a class action." Brady v. Thurston Motor Lines, 726 F.2d 136, 145 (4th Cir. 1984) (internal quotations omitted). Generally, classes consisting of forty or more members are considered sufficiently large to satisfy the impracticability requirement. See, e.g., Meijer, Inc. v. Warner Chilcott Holdings Co. III, Ltd., 246 F.R.D. 293, 301 (D.D.C. 2007) (quoting Thomas v. Christopher, 169 F.R.D. 224, 237 (D.D.C. 1996)) (finding numerosity requirement satisfied by class of thirty members). Although Plaintiffs have proffered a class of forty-four members, not all of them are sufficiently similar in their purchasing patterns to litigate as a class.

a. Size of the Class

Plaintiffs initially argue that with forty-four proposed class members, joinder is presumptively impracticable. See Pls.' Mem. Supp. Mot. to Certify Class 11-13 (ECF No. 192). Defendants counter that the class should be no larger than eighteen (18) members. See Defs.' Mem. Opp'n Mot. to Certify Class 4-8 (ECF No. 240). After considering the parties' evidence and argument, the court believes that thirty-two of the forty-four proposed members are appropriate for certification as the class Plaintiffs propose.

Defendants' attempts to pare down the class size is threefold. First they argue that the ten generic-only purchasers do not have standing to sue because they did not buy their generics from Pfizer directly, and any overcharge they paid is not the result of Pfizer's conduct. Id. at 5-6.

Defendants also argue that Plaintiffs "double-counted" entities that are subsidiaries or assignees of other proposed class members. Id. at 7. And finally, Defendants argue that class members who suffered no economic injury and brand-only purchasers should be excluded. Id. at 8-9. The report considers each of these arguments in turn.

i. Generic-only Purchasers

The court agrees that the ten generic-only purchasers should be excluded, but not because they lack standing. Rather, the ten generic-only purchasers should be excluded because Plaintiffs have failed to produce sufficient evidence to show that any overcharges paid by the generic-only purchasers were a result of Pfizer's alleged anticompetitive conduct.

Plaintiffs argue that purchasers which bought only generic celecoxib still paid higher prices for the drugs because of delayed generic entry into the market. Specifically, their expert Dr. Leitzinger argues that earlier generic entry would have allowed more time for the price of the generics to fall so that by December 2014 and beyond – when the first generic purchases were actually made – generic purchasers would have been paying a lower price than what they actually paid. To support this theory, Dr. Leitzinger's overcharge model assumed that four generic manufacturers would enter the market at the end of May 2014, and that a fifth and final manufacturer would enter in October 2014. See Leitzinger Report ¶ 36 (ECF No. 232). To calculate the would-be average price of generic celecoxib with four generic manufacturers before October, Dr. Leitzinger relied on the price projections of several generic manufacturers. Id. at ¶ 39. Because actual generic entry occurred with five manufacturers, Dr. Leitzinger simply "backcasted" the average price for generic Celebrex for a five-manufacturer market starting in October. Id. Using these average "but-for" prices, Dr. Leitzinger concluded that the price of generic Celebrex would have been lower than it actually was when generic entry occurred, and

that the difference between the but-for and actual price is compensable antitrust injury. Id. at ¶ 37.

Although Dr. Leitzinger's overcharge methodology, which has been approved of in other delayed-entry pharmaceutical cases,[11] is likely sufficient to show antitrust impact for a majority of the proposed class members, it fails to show by a preponderance of the evidence that the generic-only purchasers were injured by Pfizer's allegedly anticompetitive behavior. To begin with, the ten generic-only purchasers proposed as members of the class represent less than a quarter of the total number of generic-only Celebrex purchasers. See Cremieux Report ¶ 47 (ECF No. 241-1). Indeed, Plaintiffs and Dr. Leitzinger have imposed an unusual limit on the proposed class to "exclude[ ] . . . persons or entities who purchased only generic versions of Celebrex and did not obtain decreasing prices on those generic versions." Pls.' Mem. Supp. Mot. to Certify Class 2 (ECF No. 192). In other words, Dr. Leitzinger's damages data is based only on those generic purchasers which fit the theory of his model – that generic prices will decline over time after generic entry. But in applying this limitation, seventy-seven percent (77%) of the actual generic-only purchasers were excluded because they did not obtain decreasing prices. Cremieux Report ¶¶ 27, 47 (ECF No. 241-1). The fact that three-quarters of the actual buyers did not obtain declining prices over the three-month post-generic entry period significantly undercuts Dr. Leitzinger's theory that earlier generic entry would have led to continually lower prices, or that any anticompetitive conduct was a driver behind the actual prices experienced by customers which only purchased after generic entry.[12] By limiting the proposed class to those generic-only purchasers who did obtain decreasing prices, Plaintiffs have selectively limited the

[11] See, e.g., Meijer, 246 F.R.D. 293 (2007).

[12] Dr. Leitzinger's report cites to industry research that suggests generic prices decrease over time. See Leitzinger Report ¶ 21 (ECF No. 232). But as his Report recognizes, "the pricing benefits created by generic competition increase with the number of competitors." Id.

data to support their overcharge narrative. This evidence is insufficient to meet Plaintiffs' burden to show that the anticompetitive conduct caused an injury to the generic-only purchasers capable of proof with class-wide evidence.

Additionally, Dr. Leitzinger's methodology artificially enhanced the overcharge by relying on a theoretical generic-only market less favorable than the one that actually existed. As stated by Defendants' expert, Dr. Pierre-Yves Cremieux, pricing of generic drugs stabilizes after four or five competitors enter the market.[13] See Cremieux Report ¶ 25 (ECF No. 241-1). Dr. Leitzinger, in preparing his overcharge model, calculated a but-for market where there were four generic manufacturers, and then added a fifth and final manufacturer several months later. See Leitzinger Report ¶ 36 (ECF No. 232). But as recognized by Dr. Leitzinger, the actual generic-only market in this case was populated by five manufacturers immediately, and so the pricing in a four-manufacturer market is based on pricing forecasts, rather than actual sales data, of several generic manufacturers. See id. at ¶¶ 18, 39. This, in and of itself, is not necessarily an improper measure of overcharge in a but-for world. However, because there never was a four-manufacturer market for generic Celebrex, using a but-for model that relies on fewer manufacturers to show prices above those that actually existed artificially overstates the effect delayed generic entry had on the ten generic-only purchasers in this case. In other words, the data suggests – especially in light of the seventy-seven percent of purchasers excluded on the basis of their obtaining stable or increasing prices – that the generic-only market began with the full benefit of competitive pricing and would not have experienced declining prices beyond the

[13] Dr. Leitzinger argues in this rebuttal report that academic and government research, as well as the generic manufacturers' pricing forecasts shows further decreasing prices as a fifth generic manufacturer enters the market. See Leitzinger Rebuttal Report ¶ 9 (ECF No. 274). However, as discussed below, the four-manufacturer market theorized by Dr. Leitzinger artificially creates overcharge that was not suffered by the generic-only purchasers in this case. Importantly, Dr. Leitzinger's rebuttal report does not provide evidence that prices would continue to decrease after five manufacturers entered the market.

levels actually achieved. Of course, it is possible that in the but-for world, the generic market would not have begun with five manufacturers, and that there could have been some decrease in prices as other manufacturers entered the market.[14] But because generic-only purchasers entered into a market that had already achieved competitive saturation, the evidence is insufficient to show that they actually experienced an overcharge as a result of delayed generic entry.[15]

ii. Assignees and Subsidiaries

Regarding the exclusion of assignees, courts have held that a partial assignee is an appropriate member of a class. See, e.g., In re Modafinil Antitrust Litig., 837 F.3d 238, 251 (3d Cir. 2016) ("[T]here is persuasive circuit precedent establishing that partial assignees are appropriately considered to be members of a class."). According to the Third Circuit, "unless there is evidence that the class plaintiffs are seeking to artificially inflate the number of claimants, partial assignees may properly be treated as class members." Id. AHOLD USA is a partial assignee of Mckesson for purchases of brand-name Celebrex. But there has been no suggestion that AHOLD is not a separate corporate entity, or that the assignment was a sham to increase class size, and the court agrees with the Third Circuit's reasoning that they may be appropriately included as a member of the class. Similarly, although five proposed members are subsidiaries of other proposed class members, their inclusion is based on Pfizer's own transactional sales data showing their independent purchases of brand-name Celebrex. Tr. of Hr'g on Mot. to Certify Class 68:19-25, 69:1-5 (ECF No. 365); see also Cremieux Report Ex. 4 (ECF No. 241-1). The Modafanil Court's reasoning concerning partial assignees is equally

[14] Given that a generic manufacturer can achieve six months of exclusive generic sales through an ANDA, it is likely that there would have been a prolonged period of time until complete saturation in the generic market.

[15] The court's conclusion excluding the generic-only purchasers is limited to the issue of class certification. The ultimate viability of the Plaintiffs' damages theory for post-generic entry purchases with respect to the remaining class members will be decided at trial.

persuasive as applied to subsidiaries. These are separate corporate entities which separately purchased celecoxib. Unless there is evidence that Plaintiffs are trying to artificially inflate the number of class members, subsidiaries should be considered as potential class members to vindicate their own antitrust injury. Here, there is evidence to suggest that the subsidiaries made direct purchases of brand-name or generic Celebrex distinct from the purchases of their parent companies, and thus, would have suffered independent injury under the theory alleged.

iii. Net Economic Loss

Defendants next argue that certain class members must be excluded because they did not suffer a net economic loss. This is based on data suggesting certain direct purchasers paid less for celecoxib during the class period than the average "but-for" prices calculated by Plaintiffs' expert Dr. Leitzinger. As alleged by Plaintiffs, the antitrust injury is measured by the amount an entity was overcharged – the difference between the actual price and but-for competitive price – as a result of a defendant's improper conduct.[16] See Second Amend. Compl. ¶ 242 (ECF No. 185); Leitzinger Report ¶ 19 (ECF No. 232). And indeed, "[i]f a direct purchaser pays an illegal overcharge for a product, it may recover for the full amount of the overcharge." See Hanover Shoe, Inc. v. United Machinery Corp., 392 U.S. 481, 489 (1968). Defendants' argument that certain direct purchasers were not harmed is based on a misapplication of Plaintiffs' damages model.

Companies that purchased brand-name Celebrex during the delay period paid prices that varied based on several factors. High volume purchasers may have paid less than lower volume purchasers. Purchasers with long-term contracts may have paid less than single transaction

[16] Dr. Leitzinger's overcharge methodology has been applied in other delayed generic entry cases. See Leitzinger Report ¶ 35 (ECF No. 232); see, e.g., In re Wellbutrin XL Antitrust Litig., No. 08-2431, 2011 WL 3563385 *1, *7-9 (E.D. Pa. Aug. 11, 2011); In re Cardizem Antitrust Litig., 200 F.R.D. 297, 324 (E.D. Mich. 2001); Meijer, Inc., 246 F.R.D. at 311-12.

buyers. But according to Plaintiffs' argument – which is supported by their expert's analysis of the available data – all of them suffered an overcharge on those purchases, with the "overcharge" being the difference between what they actually paid and what they would have paid after generic entry. And "overcharge," for the purposes of antitrust liability, is the increase in prices caused by the anti-competitive conduct. See Meijer, 246 F.R.D. at 304 ("[A]ntitrust injury occurs and is complete when the defendant sells at the illegally high price.") (internal quotations omitted). If a particular company bought the drug at a price below the average but-for competitive price, that does not mean it suffered no antitrust injury. Dr. Leitzinger's average but-for price is calculated based on the various prices paid by all of the direct purchasers. Accordingly, class members should not be excluded on the basis that they paid less for celecoxib than the average but-for prices shown in Dr. Leitzinger's model.[17]

iv. Brand-only Purchasers

Defendants next contend that purchasers who only bought brand-name Celebrex and did not buy generic substitutes after they entered the market should be excluded because there is no evidence they would have purchased generic celecoxib in the but-for world where generic entry was not delayed. See Defs.' Mem. Opp'n Mot. to Certify Class 9 (ECF No. 240). In other words, because the evidence suggests these buyers only bought brand-name Celebrex, they were not overcharged because they would not have purchased the generics at lower prices no matter when they entered the market. But Plaintiffs have alleged, and their evidence tends to show, that brand-name Celebrex decreased in price significantly following generic entry. See Leitzinger Report ¶ 29 (ECF No. 232) ("Following generic entry, the average discount relative to

[17] Ten of the class members challenged for suffering no economic loss are generic-only purchasers which, as discussed above, should be excluded on the basis of insufficient evidence that Dr. Leitzinger's model supports any claim of antitrust impact, given the fully competitive state of the market after generic entry. See infra, Section III(A)(1)(a)(i).

[Wholesale Acquisition Cost] on Celebrex purchases increased from nine percent to over 40 percent."). As a result, brand-only purchasers who bought Celebrex during the delay period (six of the eight class members who only purchased brand-name Celebrex) would have suffered overcharges as a result of delayed generic entry. If generics entered the market in May 2014, the purchases made in the six months after this date would have been at a lower price due to larger discounts offered on brand-name Celebrex after generic entry.

For this same reason, however, two of the brand-only purchasers[18] – both of which only made brand purchases after generic entry – should be excluded from the class. According to Dr. Leitzinger's analysis, these post-generic-entry purchasers obtained the benefit of discounted brand-name Celebrex. If true, then they would not have paid any overcharge during the class period, and thus not suffered any antitrust impact as a result of delayed generic entry litigated in the class action. Dr. Leitzinger's hypothesis to contradict this fact is that over time, discounts on brand-name Celebrex would increase. See Leitzinger Report ¶ 41 (ECF No. 232). But in this case, five generic manufacturers entered the market simultaneously and the changes to price, discount from WAC on the brand, and market-share were rapid and widespread. Under these circumstances, Plaintiffs have not produced sufficient evidence to show that earlier generic entry would have resulted in greater discounts to brand-name Celebrex in the months the purchases in question were made.[19] As a result, the evidence suggests that these two brand-only purchasers

[18] The two brand-only purchasers with only post-generic entry purchases are Drogueria Las Rosas and Lifeline Pharmaceuticals. See Cremieux Report Ex. 4 (ECF No. 241-1).

[19] Dr. Leitzinger explains that he calculated overcharge amounts for brand purchasers by taking the average discount on brand-name Celebrex during the first quarter after generic entry (December 2014 through February 2015) and applying it to the first quarter of the delay period (May 2014 through July 2014). See Leitzinger Report ¶ 41 (ECF No. 232). He then took the average brand discount from the data available in the second quarter after generic entry (March 2015) and applied that average discount to the remainder of the overcharge period. Id. However, his report and the supporting exhibits do not identify what the actual average discount off of brand-name Celebrex was in the second quarter after generic entry. Thus, it is impossible to determine, based on the evidence in the record, whether brand purchases

received the full benefit of brand-name discounts that resulted from generic entry, and should be excluded from the class because there is insufficient evidence to show they paid an overcharge as a result of the antitrust conduct alleged.

Excluding the ten generic-only purchasers and the two companies which purchased the brand-name drug only after generic entry, the proposed class is properly limited to thirty-two of the proposed forty-four members. Accordingly, the remaining numerosity analysis under Rule 23(a) will presume a class of thirty-two.

b. Impracticability of Joinder

With a class of thirty-two members, Plaintiffs fall short of the forty members where impracticability of joinder may be presumed. But, thirty-two members is still close to the presumptive threshold, and the size of the class is not the only consideration relevant to the impracticability inquiry. See Williams v. Henderson, 129 F. App'x 806, 811 (4th Cir. 2005) ("although there is no bright line rule . . . many courts have found that classes with fewer than 30 members do not justify a class action"). Among other factors that courts will consider are judicial economy, the claimants' ability and motivation to litigate as joined plaintiffs, the financial resources of class members, and geographic dispersion of class members. See, e.g., In re Modafinil, 837 F.3d at 253. In this case, these factors weigh in favor of certification.

To begin with, given the overlapping elements of the class members' claims – namely whether Pfizer violated antitrust laws by fraudulently securing the RE '048 patent – judicial economy would be served by certifying the class and allowing common evidence to be presented. Even accepting Defendants' arguments that there are individualized elements of the impact and damage analysis, those inquiries represent a small fraction of the time Plaintiffs

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made months after generic entry would have actually obtained a greater discount than what they actually already received.

intend to devote during trial. See Hr'g on Mot. Certify Class Ex. 1, at 9 (ECF No. 308) (trial calendar). The overwhelming majority of the evidence relates to Plaintiffs' claim that Pfizer intentionally misled the PTO to secure the RE '048 patent. Both sides have identified numerous expert witnesses on the subject, and the lengthy record of the reissue prosecution will be explored in great detail. The alternative to class certification would be largely duplicative litigation that relied on many of the same witnesses and much of the same evidence necessary to prove this claim. Id. Secondly, the class of thirty-two direct purchasers is comprised of companies of varying size, geographically spread across the United States and Puerto Rico. See Leitzinger Report Ex. 4 (ECF No. 232). Such geographic dispersion regularly weighs in favor of an impracticability finding. See, e.g., In re Wellbutrin XL Antitrust Litig., No. 08-2431, 2011 WL 3563385 *1, *3 (E.D. Pa. Aug. 11, 2011).

Additionally, the resources and competitive position of most of the proposed class members would discourage them from joining in a suit or pursuing their claims individually. While Defendants correctly observe that several of the class members are large, well-capitalized companies with multi-million dollar claims, and argue this gives them the incentive to separately litigate in their own name, the majority of the proposed class members have negative value claims (i.e., the expenses, including expert fees, exceed their possible recovery). See Modafinil, 837 F.3d at 258; Tr. of Hr'g on Mot. to Certify Class 114:2-25, 115:1-4 (ECF No. 365). Together, these factors weigh in favor of certification.

Several direct purchaser/delayed generic entry cases have certified classes of varying size which included many of the same members proposed here. See, e.g., In re Wellbutrin XL Antitrust Litig., 2011 WL 3563385 at *3 (33 members); In re Lidoderm Antitrust Litig., No. 14md02521, 2017 WL 679367 (N.D. Cal. Feb. 21, 2017) (approximately 52 members); In re K-

Dur Antitrust Litig., No. 01-1652, 2008 WL 2699390 (D.N.J. Apr. 14, 2008) (approximately 47 members); Meijer, Inc., 246 F.R.D. at 305-07 (30 members). Because joinder of all thirty-two class members would be impracticable due to considerations of efficiency, geography, finances, and economic motivation, the court believes that Plaintiffs have satisfied the numerosity requirement of Rule 23(a)(1).

2. Commonality

Rule 23(a)(2) requires that questions of law or fact be common to the class. "A common question is one that can be resolved for each class member in a single hearing," and does not "turn[] on a consideration of the individual circumstances of each class member." Thorn, 445 F.3d at 319 (internal quotations and citation omitted). The Supreme Court has stated that "[c]ommonality requires the plaintiff to demonstrate that the class members 'have suffered the same injury.'" Wal-Mart, 564 U.S. at 350-51 (quoting Falcon, 457 U.S. at 157). In the antitrust context, courts have generally held that an alleged conspiracy or monopoly is a common issue that will satisfy Rule 23(a)(2). See, e.g., Meijer, 246 F.R.D. at 300; Wellbutrin, 2011 WL 3563385 at *4.

In this case, there is a single alleged injury against all of the proposed class members – an antitrust violation by Pfizer that produced delayed generic entry. See Second Amend. Compl. ¶ 202 (ECF No. 185). "Generally, antitrust plaintiffs are found to have satisfied . . . [the commonality requirement] . . . as an allegation of conspiracy or monopolization will generally be treated as a 'central' or 'single overriding' issue . . . sufficient to establish a common question." Brown v. Cameron-Brown Co., 92 F.R.D. 32, 38 (E.D. Va. 1984); see also Ballard v. Blue Shield of S.W. Va., Inc., 543 F.2d 1075, 1080 (4th Cir. 1976). Because Plaintiffs have alleged that all of the proposed class members were injured as a result of Pfizer's alleged antitrust

violations, common questions of law and fact exist among all class members regarding Pfizer's conduct, which satisfies the commonality requirement of Rule 23(a)(2).

3. Typicality

Rule 23(a)(3) requires that "the claims or defenses of the representative parties are typical of the claims or defenses of the class." Fed. R. Civ. P. 23(a)(3). The typicality and commonality requirements are similar, as "[b]oth serve as guideposts for determining whether . . . the named plaintiff's claim and the class claims are so interrelated that the interests of the class members will be fairly and adequately protected . . . ." Gen. Tel. Co. of the Sw. v. Falcon, 457 U.S. 147, 157 n. 13 (1982). But the typicality requirement specifically ensures that named class representatives are appropriately part of the class and "possess the same interest[s] and suffer the same injury as the class members." Broussard v. Meineke Discount Muffler Shops, Inc., 155 F.3d 331, 338 (4th Cir. 1998). "The essence of the typicality requirement is captured by the notion that 'as goes the claim of the named plaintiff, so goes the claims of the class.'" Deiter v. Microsoft Corp., 436 F.3d 461, 466 (4th Cir. 2006) (citing Broussard, 155 F.3d at 340).

Plaintiffs argue that the proposed class members meet the typicality requirement because they all assert injury stemming from the same conduct – Pfizer's fraudulent securing of the RE '048 patent and subsequent litigation against the generic manufacturers. Pls.' Mem. Supp. Mot. to Certify Class 14-15 (ECF No. 192). Defendants respond that the differing categories of class members – namely the generic-only purchasers, and the vastly different purchasing power among certain proposed members – render them atypical from one another, and from the named Plaintiffs. See Defs.' Mem. Opp'n Mot. to Certify Class 16-18 (ECF No. 240). But the generic-only purchasers should not be included for reasons described elsewhere.[20] And with respect to

[20] As set forth in Section A(1)(a)(i), the Plaintiffs have failed to satisfy their burden to show the generic-only purchasers suffered an antitrust injury capable of being measured by class-wide proof. The injury asserted by them

the remaining members, the typicality "requirement has been liberally construed by courts . . . [and] in the antitrust context, typicality 'will be established by plaintiffs and all class members alleging the same antitrust violations by defendants.'" In re Vitamins Antitrust Litig., 209 F.R.D. 251, 260 (D.D.C. 2002) (quoting In re Playmobil Antitrust Litig., 35 F. Supp. 2d 231, 241 (E.D.N.Y. 1998)); see also Meijer, 246 F.R.D. at 301. "[I]f the claims of the named plaintiffs and putative class members involve the same conduct by the defendant, typicality is established regardless of factual differences." Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc., 259 F.3d 154, 183-84 (3d Cir. 2001); see also In re K-Dur, 2008 WL 2699390 at *5.

In this case, while the representative Plaintiffs and putative class members may be factually distinguishable in the way they purchased celecoxib before and after generic entry, they all allege the same type of injury stemming from the same conduct. See Second Amend. Compl. ¶ 242 (ECF No. 185); see also Leitzinger Report ¶¶ 19, 37 (ECF No. 232). That is, both the representative Plaintiffs and the proposed class members all claim that they suffered overcharges as a result of Pfizer's conduct which delayed generic entry into the market. Id. This makes the claims of the representative Plaintiffs typical of the class members' claims, such that their interests "are so interrelated that . . . the class members will be fairly and adequately protected . . ." Falcon, 457 U.S. at 157 n.13 (1982). Because the representative Plaintiffs' claims of antitrust conduct are identical to the claims of all the proposed class members, Plaintiffs have satisfied the typicality requirement of Rule 23(a)(3).

4. Adequacy

The final requirement under Rule 23(a) is that the parties representing the proposed class be able to "fairly and adequately . . . protect the interests" of all members of the class. Fed. R.

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is also not typical of the other class members as they allege a diminimus overcharge based on a selective examination of the data. As a result, their lack of typicality offers an additional reason to exclude them.

Civ. P. 23(a)(4). This inquiry "serves to uncover conflicts of interest between named parties and the class they seek to represent." Amchem Prod., Inc. v. Windsor, 521 U.S. 591, 625 (1997) (citing Falcon, 457 U.S. at 157-58 n.13). In order for a conflict to defeat class certification, the conflict "must be more than merely speculative or hypothetical," but rather "go to the heart of the litigation." Gunnells, 348 F.3d at 430-31 (internal quotations and citations omitted).

Plaintiffs argue that the representative Plaintiffs more than adequately protect the interests of the class members, and that there is no cognizable conflict between any of the representative Plaintiffs and proposed class members. See Pls.' Mem. Supp. Mot. to Certify Class 15-16 (ECF No. 192). Defendants argue that economic conflicts exist among the representative Plaintiffs and class members because some class members actually benefited financially from delayed generic entry. See Defs.' Mem. Opp'n Mot. to Certify Class 18-21 (ECF No. 240). Specifically, Defendants allege that some of the purchasers benefited from delayed generic entry because they were able to avoid "generic bypass."[21] Id. Defendants also argue that there is a conflict between members concerning the overcharge period because for some companies, viewing purchases over the entire 10-month class period, show no economic loss. See id. at 21. For example, Defendants' expert, Dr. Cremieux, argues that during the delay period (May 2014 to December 2014), class member ANDA/Watson suffered $1.9 million in overcharges. See Cremieux Report Ex. 5 (ECF No. 241-1). But the same class member has "negative" damages of -$11.1 million when the full overcharge period (May 2014 to March 2015) is applied. See id. Defendants cite to Plotnick v. Computer Scis. Corp., 182 F. Supp. 3d 573, 584 (E.D. Va. 2016), for the proposition that the adequacy requirement of Rule 23(a)(4) is not satisfied where some class members economically benefited from the alleged conduct. And

[21] "Generic bypass" refers to the practice of consumers (e.g., pharmacies) buying generic drugs directly from manufacturers rather than wholesalers. See Leitzinger Report ¶ 45 (ECF No. 232). As a result of "generic bypass," wholesalers can lose a significant volume of sales when generics enter the market.

indeed, Plotnick – an ERISA class action suit – appears to endorse the Eleventh Circuit's decision in Valley Drug Co. v. Geneva Pharmaceuticals, Inc., 350 F.3d 1181, 1190 (11th Cir. 2003), which reversed class certification where some of the members benefited economically as a result of generic bypass in a delayed generic entry case. See 182 F. Supp. 3d at 585.

However, as discussed above, antitrust injury in this case is expected to be measured by the amount an entity was overcharged – the difference between the actual price and would-be competitive price – as a result of a defendant's improper conduct. See Second Amend. Compl. ¶ 242 (ECF No. 185); Leitzinger Report ¶ 19 (ECF No. 232). And the Valley Drug decision, which is not binding here, has been criticized for failing "to appreciate the true import of the Hanover Shoe rule that a direct purchaser may recover the full amount of the overcharge, even if he is otherwise benefitted, because the antitrust 'injury occurs and is complete when the defendant sells at the illegally high price.'" Meijer, 246 F.R.D. at 304 (quoting In re Cardizem CD Antitrust Litig., 200 F.R.D. 297, 313 (E.D. Mich. 2001)); Hanover Shoe, 392 U.S. at 489 ("[i]f a direct purchaser pays an illegal overcharge for a product, it may recover for the full amount of the overcharge."). This critique is persuasive. The fact that some class members may have experienced an economic gain as a result of delayed generic entry, or that a company did not suffer a net loss due to overcharges, does not create a material conflict which will defeat class certification. See Meijer, 246 F.R.D. at 304; In re Wellbutrin, 2011 WL 3563385 at *16 (holding that generic bypass arguments do not defeat certification and can be accommodated by Dr. Leitzinger's damages model). The relevant issue on class certification is whether the named members of the class and the absent class members suffered the same type of overcharge as a result of Pfizer's conduct – that is when the injury is complete and liability attaches. Id.

In addition to there being no legitimate conflict between the class members, the court also believes that the representative Plaintiffs will adequately and fairly represent the class. Both ASC and RDC have been deemed adequate class representatives in similar cases. See, e.g., In re Lidoderm, 2017 WL 679367. Plaintiffs' counsel also has extensive experience handling antitrust litigation where generic suppression is alleged. See Mem. Supp. Mot. Appointment of Class Counsel (ECF No. 17). And thus far, Plaintiffs' counsel appears to have sufficient resources – both financial and legal – to prosecute the case diligently on behalf of the entire proposed class. Because there is no material conflict between the representative Plaintiffs and/or class members, and because the representative Plaintiffs and counsel are well equipped to represent the class members, the adequacy requirement of Rule 23(a)(4) is satisfied.

B. Rule 23(b)

In addition to meeting all the requirements of Rule 23(a), Plaintiffs must also satisfy one of the three criteria in Rule 23(b). Plaintiffs here are seeking certification under Rule 23(b)(3), which requires the court to find that (1) "the questions of law or fact common to class members predominate over any questions affecting only individual members," and (2) "that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." Fed. R. Civ. P. 23(b)(3). The court addresses this two pronged inquiry in turn.

1. Predominance

To meet the predominance requirement, Plaintiffs must show by a preponderance of the evidence that the elements of their claim can be proven by evidence common to the members of their class. See In re Hydrogen Peroxide, 552 F.3d at 311-12. Plaintiffs are not required "to prove that each 'elemen[t] of [their] claim [is] susceptible to classwide proof,'" but only that "common questions 'predominate over any questions affecting only individual [class]

members.'" Amgen Inc. v. Conn. Retirement Plans and Trust Funds, 568 U.S. 455, 469 (2013) (quoting Fed. R. Civ. Proc. 23(b)(3)). The elements of Plaintiffs' antitrust claims are (1) a violation of the antitrust laws, (2) individual injury or antitrust impact, and (3) measurable damages. Id. at 311. In this case, common questions of fact and law predominate over any individualized inquiry in each element of Plaintiffs' antitrust claims.

a. Violation of Antitrust Law

First, Plaintiffs allege that Pfizer violated Section 2 of the Sherman Act by "knowingly engag[ing] in an anticompetitive scheme designed to block and delay entry of AB-rated generic version [sic] of Celebrex to maintain its monopoly power." Pls.' Mem. Supp. Mot. to Certify Class 17 (ECF No. 192). Under Section 2 of the Sherman Act, "[e]very person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person . . . to monopolize any part of the trade" is liable under the Act. 15 U.S.C. § 2. "To prove a Section 2 monopolization offense, a plaintiff must establish two elements: (1) the possession of monopoly power; and (2) willful acquisition or maintenance of that power – as opposed to simply superior products or historic accidents." E.I. du Pont de Nemours and Co. v. Kolon Industries, Inc., 637 F.3d 435, 441 (4th Cir. 2011) (citing Eastman Kodak Co. v. Image Technical Servs., Inc., 504 U.S. 451, 480 (1992)). "An attempted monopolization offense consists of: (1) the use of anticompetitive conduct; (2) with specific intent to monopolize; and (3) a dangerous probability of success. Id. (citing Spectrum Sports, Inc. v. McQuillan, 506 U.S. 447, 456 (1993)).

Courts deciding whether to certify a class in delayed-entry cases like this one frequently find that common questions of fact and law will predominate when there has been an alleged violation of antitrust law. See, e.g., In re Wellbutrin, 2011 WL 3563385 at *6 ("If each class member pursued its claims individually, the class member would have to prove the same

antitrust violations using the same documents, witnesses, and other evidence."). And in fact, as is true in this case, predominance of common issues in determining antitrust violations is rarely contested. See id.; see also Meijer, 246 F.R.D. at 308; In re K-Dur, 2008 WL 2699390 at *12.

In this case, all of the proposed class members have alleged harm from delayed generic entry, which they say resulted from Pfizer's fraudulent prosecution of the reissue application leading to the RE '048 patent. Plaintiffs claim that Pfizer fraudulently obtained the reissue patent by misrepresenting both the purpose for seeking reissue and the prosecution history of the underlying patents, while knowing that it was not entitled to such an extension under the law.[22] By wrongfully securing the RE '048 patent, Plaintiffs argue, Pfizer was able to prolong the exclusivity of brand-name Celebrex and prevent entry of generic competitors – monopolizing the market for celecoxib drugs. Proving these claims will require common evidence and witnesses, and the outcome will not be affected by any individual circumstance of a particular class member.[23] Of the three weeks scheduled for trial, Plaintiffs devote two full weeks to proving that Pfizer violated antitrust laws by fraudulently securing the RE '048 patent, and thereby extending its monopoly on the Celebrex market. See Hr'g on Mot. Certify Class Ex. 1, at 9 (ECF No. 308) (trial calendar). By comparison, Plaintiffs anticipate taking four days to address the issue of impact and two days for damages. Id. Additionally, a majority of the twenty-six witnesses identified by the parties are slated to testify on issues regarding antitrust violation. See Hr'g on Mot. Certify Class Ex. 1, at 10 (ECF No. 308).

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[22] Plaintiffs also argued that Pfizer engaged in sham litigation to prevent generic entry into the market. And Pfizer did, in fact, sue the major generic manufacturers who had filed ANDAs for Celebrex the same day the PTO issued the RE '048 patent. However, Plaintiffs' sham litigation claim was dismissed by the district court. See (ECF No. 73).

[23] A list of fact witnesses offered by Plaintiffs at the hearing on the Motion to Certify Class highlights that all of the factual testimony regarding the alleged antitrust violation will come from current or former Pfizer attorneys who were involved in the patent prosecution. See Hr'g on Mot. Certify Class Ex. 1, at 10 (ECF No. 308). In other words, there are no fact witnesses who will offer testimony individualized to a particular class member on the issue of antitrust violations.

Based on this common evidence, the legal issues surrounding the antitrust violation will also be resolved uniformly across the class – whether Pfizer violated antitrust laws does not depend on any legal issue unique to a particular class member. Accordingly, Plaintiffs have proven by a preponderance of the evidence that common issues regarding the antitrust violation predominate over any individualized inquiry. See Amgen, 568 U.S. at 469.

b. Antitrust Impact

To show antitrust impact, there must be sufficient evidence to show that the class members suffered "some damage" as a result of Pfizer's alleged antitrust violation. See E.I. du Pont Nemours, 637 F.3d at 441. Plaintiffs allege that all of the class members have suffered injury in the form of overcharges as a result of Pfizer's anticompetitive conduct which led to delayed entry of generic Celebrex into the market. See Pls.' Mem. Supp. Mot. to Certify Class 19 (ECF No. 192). Specifically, Plaintiffs' expert argues that:

> The onset of generic competition at an earlier date would have reduced the amounts paid for celecoxib by direct purchasers in three ways: i) much of the Celebrex purchase volume during the delay period would have been replaced with generics at much lower prices; ii) the remaining Celebrex purchases would have occurred at lower average prices; and iii) generics purchased following actual generic entry would have had still-lower prices by virtue of the fact that, in the but-for world generic competition would have started earlier.

Leitzinger Report ¶ 37 (ECF No. 232).

Dr. Leitzinger's report makes several foundational conclusions regarding the market for generic pharmaceutical drugs that are relevant to the issue of antitrust impact. First, Dr. Leitzinger concludes based on academic and government research that generic drugs enter the market at significantly lower prices than the brand drug they emulate, and that generic drugs quickly capture a large market share. See id. at ¶ 20. In addition, his report concludes that the entry of generic drugs leads to reduction in the price of the brand-name drug itself. Id. at ¶ 22.

Dr. Leitzinger also relied upon the market forecasting data and actual transactional sales data to conclude that, upon entry of generic Celebrex into the market, the generics did in fact capture a significant portion of sales, and the prices for both generic and brand Celebrex decreased. Id. at ¶ 24. Plaintiffs argue that all of this evidence is common to the class, and would predominate over any individualized inquiry.

Defendants counter by arguing that questions of individual impact would predominate, and that the evidence offered by Plaintiffs is overgeneralized to appear common. See Mem. Opp'n Mot. to Certify Class 22 (ECF No. 240). Defendants' arguments largely focus on the categories of class members – as discussed above – that it sought to exclude. For example, Defendants argue that the common evidence for most class members would not apply to the ten generic-only purchasers, and that an extensive individualized inquiry would be required to determine whether it was anticompetitive conduct as opposed to some other market forces (e.g., sales volume or relationships with generic manufacturers) that caused price variations among generic-only purchasers. Id. at 23-24. Defendants also argue that because some proposed class members did not suffer economic loss, an individual inquiry would be necessary to determine which members were actually impacted. Id. at 23.

Given the class of thirty-two this Report recommends, the remaining class members' evidence of antitrust impact is common, and would predominate over any individual inquiry. It is beyond contest that generic drugs cost less than their branded counterparts, and that generic drugs capture a significant – if not overwhelming – share of the market upon entry. It is also undisputed that brand-name drugs are often discounted as a result of generic entry. The events surrounding the generic entry of the celecoxib documented in the record to date suggest that these foundational principles were borne out in this case. See Leitzinger Report ¶¶ 28-30 (ECF

No. 232). The theory of impact proposed by Plaintiffs is overcharge caused by delayed generic entry. See Pls.' Mem. Supp. Mot. to Certify Class 19 (ECF No. 192). Thus, evidence concerning the price of branded Celebrex before and after generic entry, the price of generic drugs, and the volume of each drug sold is common evidence relevant to impact among the remaining class members. That is to say, purchasers who bought both generic and brand-name Celebrex, and brand-only purchasers who bought the drug before generic entry could all rely on the same evidence to show that delayed entry of generic drugs caused them to pay more for Celebrex than they might have but for Pfizer's alleged conduct.

Many of Defendants' arguments on the necessity for individual evidence of antitrust impact are rendered moot by the court's proposed limiting of the class.[24] However, Defendants continue to argue that some of the proposed class members were not injured by delayed generic entry, and thus those uninjured members necessitate an individualized inquiry. Defs.' Mem. Opp'n Mot. to Certify Class 23 (ECF No. 240). Defendants may be correct that an individualized inquiry would be necessary if net economic performance was the proper measure of injury in this case. However, as discussed above, antitrust injury here is measured by the amount an entity was overcharged – the difference between the actual price and would-be competitive price – as a result of Pfizer's allegedly improper conduct. See Meijer, 246 F.R.D. at 304. Accordingly, Plaintiffs have shown by a preponderance of the evidence that common evidence of antitrust impact will predominate over any individual issues.

c. Measurable Damages

To meet the measurable damages element, Plaintiffs must show that damages can be reliably measured on a class-wide basis. See Comcast Corp. v. Behrend, 133 S. Ct. 1426, 1433 (2013). The class-wide methodology employed must only measure "those damages attributable

[24] See infra Section A(1)(a)(i) and n. 20

to" the theory of antitrust impact put forward by Plaintiffs. Id. In this case, Plaintiffs have alleged that they suffered overcharge as a result of delayed generic entry. Thus, Plaintiffs' methodology for measuring damages must be able to determine the approximate overcharge suffered by each class member. The court believes that Plaintiffs have met their burden of showing by a preponderance of the evidence that overcharge damages can be measured on a class-wide basis and will predominate over any individualized inquiry.

Damages calculations need not be exact, but must still be consistent with the theory of liability. See id. In Comcast, sixteen counties in Pennsylvania, Delaware, and New Jersey sued Comcast, arguing that it had violated antitrust laws by monopolizing the cable T.V. market in the respective areas. Id. at 1430. The Supreme Court overturned a class certification on the basis that the damages model proposed by the plaintiffs could not be applied on a class-wide basis. See id. at 1433. Much like the damages model sought to be applied in this case, the plaintiffs in Comcast sought to measure the difference between a but-for competitive price and the actual amounts paid by the class members. Id. at 1434. However, unlike this case, the damages model in Comcast assumed the validity of other antitrust claims made against the defendants – that the but-for price was affected by decreased market penetration of satellite providers, lack of benchmark competition, and increased bargaining power. Id. In other words, the but-for price used in the Comcast damages model assumed that it would be at a particular level absent all of the alleged antitrust conduct, despite the fact that the class had only been certified to proceed on one theory of antitrust violation. Thus, the Supreme Court held that the methodology was flawed because it did not isolate the measurement to the theory of liability certified for class adjudication.

Although this case involves different categories of overcharge, it is unlike Comcast because the overcharges here all result from the same alleged antitrust violation. That is to say, Plaintiffs here have alleged that all of the overcharges suffered – whether by brand/generic purchases or brand-only purchasers – are a result of delayed generic entry caused by Pfizer's alleged antitrust violation. Plaintiffs have not asserted multiple theories of liability that would cause the aggregate but-for prices to fluctuate based on the validity of any particular theory. The aggregate but-for competitive prices of brand and generic Celebrex turns solely on a single issue of liability. And indeed, the only catalyst in Dr. Leitzinger's model is whether there was delayed generic entry – the market forces that cause brand and generic prices to reach an aggregate competitive price are constants that are common to the class. While some companies may have paid different prices due to volume or pre-existing relationships, the fact that aggregate prices may have been higher due to delayed generic entry is what is relevant to this analysis. It is also worth noting that Dr. Leitzinger's model has been approved in other delayed entry cases. See, e.g., Lidoderm, 2017 WL 679367, at *12; Provigil, 309 F.R.D. at 212-14; Wellbutrin XL, 2011 WL 3563385, at *12-16; K-Dur, 2008 WL 2699390, at *14-15; Meijer, 246 F.R.D. at 310-12.

Defendants contend that individual issues will nonetheless predominate because Plaintiffs seek to create an "aggregate pot" of damages, which they argue will lead to improper compensation of some class members. See Mem. Opp'n Mot. to Certify Class 28 (ECF No. 240). Defendants cite Windham v. Am. Brands, Inc., 565 F.2d 59, 72 (4th Cir. 1977), for the proposition that aggregate damages or "fluid recovery" is not permitted in antitrust class action suits. First, it is not at all clear that the Fourth Circuit proscribed any particular method of calculating class damages by its criticism of "fluid recovery" in Windham. That case was expected to involve 20,000 individual class members asserting price-fixing claims against seven

buyers of cured tobacco, and the decision to deny class certification "primarily turned upon a finding of the unmanageability of the class." Id. at 65. In affirming the district judge's finding, the court noted the "highly individualized character" of the damages inquiry, which the district judge believed would demand a "mini trial in all the individual claims." Also relevant, the plaintiffs asserted that "they 'expect' to develop a formula which will simplify the computation of individual damages, at some point later in the litigation." Id. at 70.

By contrast, this case involves a recommended class of thirty-two individual claimants, each of which has already been identified as a direct purchaser of brand or generic celecoxib. In addition, the Plaintiffs rely upon a widely-accepted mathematical formula for assessing damages with class wide proof. Meijer, 246 F.R.D. at 311-12; Cardizem, 200 F.R.D. at 348-49. The fact that individualized inquiry may be necessary to allocate those damages will not defeat class certification. Cardizem, 200 F.R.D. at 348. Accordingly, Plaintiffs have met their burden of showing by a preponderance of the evidence that damages can be reliably measured on a class-wide basis.

2. Superiority

The superiority requirement ensures that proceeding by class action will "achieve economies of time, effort, and expense, and promote . . . uniformity of decision as to persons similarly situated, without sacrificing procedural fairness or bringing about other undesirable consequences." Amchem, 521 U.S. at 615.

The superiority requirement is met in this case. As discussed above with respect to impractability of joinder, this case involves complex issues of fact and law that are common to the class members. Adjudicating the class members' claims individually would be unnecessarily time consuming, expensive, and duplicative. As proffered during the hearing on this Motion, a

majority of the trial will be devoted to the question of whether Pfizer violated antitrust law by fraudulently securing the RE '048 patent. See Hr'g on Mot. to Certify Class Ex. 1 (ECF No. 308, at 9). And most of the fact and expert witnesses would be the same in the individual cases. See Hr'g on Mot. Certify Class Ex. 1 (ECF No. 308, at 10). Moreover, class resolution will ensure that all affected and properly certified class members are able to pursue valid antitrust claims where they might otherwise be financially prevented from doing so.

Although class litigation departs from the general rule that individuals pursue their claims individually, in the complex context of delayed generic entry the benefits of Rule 23 have been widely recognized. Meijer, 246 F.R.D. at 314; Relafin, 218 F.R.D. at 347; K-Dur, 2008 WL 2699390 at *21. Plaintiffs have met their burden of showing by a preponderance of the evidence that proceeding under class action is superior to individual suits because it will avoid duplicative, expensive, and potentially inconsistent adjudication of the common claims.

IV. RECOMMENDATION

For the foregoing reasons, the court recommends the district court GRANT IN PART and DENY IN PART Plaintiffs' Motion to Certify Class (ECF No. 191), and certify a class of thirty-two members comprised of those direct purchasers of Celebrex which purchased brand-name and/or generic versions of the drug during the class period as specified in this Report. For the reasons stated, the court should exclude from the class-proposed members which only purchased generic forms of the drug from non-parties after generic entry, and the two proposed members which purchased only brand-name Celebrex after generic entry.

V. REVIEW PROCEDURE

By copy of this report and recommendation, the parties are notified that pursuant to 28 U.S.C. § 636(b)(1)(C):

1. Any party may serve upon the other party and file with the Clerk written objections to the foregoing findings and recommendations within fourteen (14) days from the date of mailing of this report to the objecting party, see 28 U.S.C. § 636(b)(1), computed pursuant to Rule 6(a) of the Federal Rules of Civil Procedure. Rule 6(d) of the Federal Rules of Civil Procedure permits an extra three (3) days, if service occurs by mail. A party may respond to any other party's objections within fourteen (14) days after being served with a copy thereof. See Fed. R. Civ. P. 72(b)(2) (also computed pursuant to Rule 6(a) and (d) of the Federal Rules of Civil Procedure).

2. A district judge shall make a de novo determination of those portions of this report or specified findings or recommendations to which objection is made.

The parties are further notified that failure to file timely objections to the findings and recommendations set forth above will result in a waiver of appeal from a judgment of this Court based on such findings and recommendations. Thomas v. Arn, 474 U.S. 140 (1985); Carr v. Hutto, 737 F.2d 433 (4th Cir. 1984); United States v. Schronce, 727 F.2d 91 (4th Cir. 1984).

/s/
Douglas E. Miller
United States Magistrate Judge

DOUGLAS E. MILLER
UNITED STATES MAGISTRATE JUDGE

Norfolk, Virginia

July 28, 2017